Purpose: This document was created to serve as a how-to guide and resource to help integrated health system specialty pharmacies (IHSSPs) create and manage a successful Risk Evaluation and Mitigation Strategy (REMS) compliance program. The how-to guide is split into three chapters including "getting started", "day-to day operations", and "audits and compliance". Each chapter contains questions/concepts to consider and best practice tips. Example documents are also included and listed as appendices.

Chapter 1: Getting Started

Questions to consider:
• Oversight:
  ○ Who will be overseeing the REMS compliance program?
  ○ Will this program manage both inpatient and outpatient REMS operations? Do buy-and-bill practices and/or clear bagging occur? Is alignment needed?
  ○ For sites with more than one pharmacy, will all sites dispense REMS medications?
  ○ Which REMS medications is the organization currently dispensing (many only require a med guide) and what is the estimated volume of patients?
  ○ What are the REMS requirements of each medication?
  ○ Does the organization have access to desired REMS medications on the wholesaler accounts (consider WAC, 340B, GPO)?
  ○ Who will be (or is currently) listed as the authorized representative on each REMS medication? Are updates needed? Will this be the same individual overseeing the REMS compliance program?
  ○ Will customizations be necessary in your dispensing systems and/or the EHR system or other documentation system?
  ○ Does your organization have a clearly explained and implemented process for reporting adverse events?
  ○ How will your organization identify and implement new requirements and/or new REMS medications? Who is responsible for each step of the process (identifying, implementing, educating)?

• Best practice tips:
  ○ REMS program scoping: Consider partnering with inpatient and clinic compliance teams to ensure implementation of their own P&P, when appropriate.
  ○ The REMS authorized representative should be an individual capable of overseeing the implementation and ongoing compliance of the REMS program.
  ○ Be sure to determine a backup authorized representative in the case of extended PTO or turnover.

- Clearly document the process for ensuring the new authorized representative is properly trained and in place before the initial authorized representative vacates the position.
- Consider adding REMS responsibilities to the appropriate job description(s). Be sure to differentiate specific responsibilities (day-to-day operations vs. oversight/auditing). Depending on your organization and workflows, this may be a single individual or may be multiple.
- Consider developing a clear process of identifying new REMS medications or new requirements promptly to eliminate risk. This could be incorporated into the new medication training process to ensure Pharmacy REMS enrollment occurs early in the process.

Chapter 2: Day to Day Operations

Questions to consider:

- Policies and Procedures:
  - How will your institution handle this requirement? Will a single Policy suffice, or will each REMS require a Standard Operating Procedure? (See Appendix I)
  - How will you determine and define "relevant staff" (i.e., by job description or role)?
- Operations:
  - How will your staff know which drugs are subject to REMS?
  - How will you ensure that your front-line staff complete all predispense requirements?
  - How will each audited requirement be documented to prove compliance?
  - Do all relevant staff have the necessary access to portals to complete the REMS related tasks?
  - Is the REMS drug also LDD, and will your institution have additional requirements beyond the REMS?
  - How will you provide ongoing training and education for relevant staff?

- Best practice tips:
  - Policies and procedures should be concise and be readily available to relevant staff and auditors.
  - Most REMS require training of 'relevant' staff, with 'relevant' to be defined by the pharmacy. Consider defining the procedure for identifying and training relevant staff in your SOP.
  - If the REMS has an online portal, ensure that anyone with access to the portal has completed training.
  - Consult the REMS document to determine if any REMS-issued materials must be used to train staff, and ensure the current version is used in training. Note that auditors may ask to see training content.
  - Ensure ALL required staff are trained since auditors may request to see log of trained individuals.

- Consider publishing a separate SOP for every REMS that has an ETASU with pharmacy-specific requirements. Use the FDA-approved REMS document as a guide for activities that should be included (e.g., training, record retention, transfer of REMS drug). Ensure staff review of this SOP is documented.
- Consider providing quick reference guides to your staff with REMS requirements (including delivery windows, if applicable).
- Consider technological aids (e.g., flags, groupers, hard stops, assessments) to identify drugs with REMS and prompt documentation of dispensing requirements. (See Appendix III)
- Auditors will expect to see proof that all requirements occurred for each dispense. Consider adding line items in dispensing software as proof required documentation was given to patient. (See Appendix III)
- Consider including contractual requirements, if applicable, in the REMS SOP, being sure to outline the more restrictive requirements (e.g., timeframe for reporting Adverse Events) if there is a conflict with organization's policy.
- New REMS medication identification – clearly indicate job responsibility for new medication identification and process for REMS. Many times this comes from front line team. Ensure there is process for identifying new medications and follow up to ensure requirements for new medication are met (LDD, REMS)
- Include REMS identification on new medication training documentation and/or proactive risk assessment forms. Consider timeline creation to ensure all medication onboarding steps are completed.

Chapter 3: Audits and Compliance

Questions to consider:

- How do you plan to store documentation related to REMS? Will storage be within dispensing software? What will be stored in additional audit files?
- Who will be responsible for reviewing changes to REMS requirements and communicating them with staff, providers, and patients?
- Who will be responsible for updating documentation (i.e., policy, procedures, training) when necessary?
- If complaints or corrective actions occur, where will you document and store those?
- How often will self-audits of REMS compliance be completed? What volume of dispenses will be audited? (See Appendix II)
- What will be the process to communicate audit results to relevant staff?
- What will be the process to promptly mitigate compliance risk or breaches?
- How will you document completion of required training for all relevant staff and where will it be stored?
- How will you show documented proof of all REMS requirements? Will you provide screenshots or live navigation?

- Who will be involved in the audit? Will the authorized representative lead the audit alone or will other members of the staff and/or compliance team be included?
- What policies or procedures will you provide to detail your organization's facility safety procedures (i.e., fire safety, badge access, alarm systems)?

- Best practice tips
  - Many REMS medications with ETASU require generation of authorization codes prior to dispensing. These codes should be stored in a consistent location for ease of access during an audit. Depending on your operations, it may be helpful to store in more than one location (e.g., in dispensing software for front-line staff and in therapy management system for compliance team)
  - Consider creating a compliance checklist for each medication to use with training and during self-audits.
  - Subscribe to FDA REMS email updates
  - Consider the complexity of the REMS when determining frequency for audits. Many REMS programs will audit participating pharmacies within first six months of certification and annually thereafter; self-auditing at least annually provides an option to identify potential issues. Ensure audit responsibility is clear in job descriptions
  - Ensure all REMS related policies, procedures, training documents, complaints/corrections are readily available for REMS Compliance Audits.
  - Audit non-REMS certified pharmacies within your institution to ensure no dispenses
  - As part of audit process, check FDA website see if any updates to the REMS program
  - For REMS medications with RDAs, ensure all RDAs are associated with a dispense. This can be done by logging into REMS portal, downloading all historical RDAs, and comparing them to dispense data.

Example Documents

- Appendix I: Medication Specific REMS SOP/Policy Template
- Appendix II: Audit Tool
- Appendix III: Dispensing System Hard Stops and Proof of Required Documentation

Appendix I: Medication Specific REMS SOP/Policy Template

I. Process or Procedure
   a. Authorized Representative (AR)
      i. The Role of the AR, the activities the AR is responsible for, and a plan for AR succession should be defined
      ii. This information can be included here or under a separate section if appropriate (e.g. some institutions have a designated section for "Responsibility" of carrying out the SOP)
   b. Training
      i. Who is trained?
      ii. What is included in the training (i.e. name the specific document required by the REMS, if applicable)?
   c. Counseling Process
      i. Not required for all REMS programs
      ii. May include counseling, drug interaction screens, or verification of lab work
   d. Dispensing
      i. Include the method(s) by which your pharmacy verifies that required steps are completed prior to dispensing
      ii. Define steps that occur prior to each fill
      iii. If required, define any documentation required to be dispensed with each fill.
      iv. If a REMS Dispense Authorization (RDA) is required, define how this is obtained and what it verifies (e.g. a valid RDA verifies the patient and prescriber are enrolled)
   e. Other
      i. Adverse Event Reporting
         1. Review both the REMS Document and any contractual requirements to define what must be reported and in what timeframe.
         2. Include the method by which AEs are identified.
      ii. Transfer of Stock
         1. Is it allowed?
         2. How would certification of transfer partner be verified?
      iii. Records Retention
         1. May reference an institutional policy on timeframe of retention
         2. If the REMS Document lists items that must be included in records, consider defining them here.

II. Miscellaneous
   a. Include relevant information per your institution's SOP template, such as references, committee approval, lead author, etc.

QUICK TIPS

Consider a narrow applicability, especially if the medication may be handled by other teams in your organization

Consider whether a Policy or Standard Operating Procedure (SOP) is appropriate. An SOP limited to a single department can generally be modified and approved more quickly than a policy, especially in a large institution.

Before writing a REMS SOP, download the REMS Document from REMS@FDA and locate any contractual agreement your institution may have with the drug manufacturer and/or REMS administrator. Use these documents to identify the required *actions for your pharmacy. Be aware that contractual requirements are often more restrictive than REMS requirements; your SOP should define a process that meets the more restrictive requirements.*

Consider maintaining an SOP for each medication your pharmacy dispenses that has pharmacy-specific ETASU (as defined in the REMS document).

Upon policy cycle review, consider validating current versions of required documents (med guides, etc.) are automatically printed with dispense or on hand for staff.

Pharmacy Name:
Medication Name:
Authorized Representative Name:
REMS policies and procedures exist?
Relevant staff defined in policies & procedures?
Proof of required training for all relevant staff, if applicable?

Prescription Number	Dispensed Date	Pharmacy required counseling documentation complete (Y/N)	Quantity/days supply dispensed meet program requirements (Y/N)	Authorization number obtained & documented (Y/N)	Required documentation provided to patient (Y/N)	Dispensed/ shipped within required timetime (Y/N)	Adverse events reported, if applicable (Y/N/NA)	Fully Compliant (Y/N)

Auditor Name:
Date Audit Completed:
Date Results Communicated:

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Appendix III: Dispensing System Hard Stops and Proof of Required Documentation